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## Chronic CAD/Stable Ischemic Heart Disease

### TRIALS IN ISCHEMIC HEART DISEASE DO NOT REPRESENT THE ISCHEMIC UNIVERSE

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**Background:** In clinical trials of revascularization the terms “coronary artery disease” and “ischemic heart disease” are sometimes used interchangeably. This can create confusion in inclusion and exclusion criteria, which may lead to uncertain results. Our purpose is to investigate if the clinical trials population comparing percutaneous coronary revascularization to medical therapy for stable ischemic heart disease reflects specifically concerns patients with demonstrable ischemia and how many patients are included in the trial with the only evidence of coronary atherosclerosis and without ischemia.

**Methods:** Individual trials data (number of patients screened, number of patients enrolled, number of patients with positive stress test or without stress test) were obtained from ACME I, ACME II, RITA I, RITA II, MASS I, MASS II, AVERT, ACIP and COURAGE. Published data were used to calculate the number of patients included in the trials with negative stress test but significant coronary artery stenosis and the number of patients excluded from the trials with positive stress test or angina (but without significant coronary artery stenosis at the time of angiography).

**Results:** More than 195,213 people have been screened from 1998 to 2011. Overall about 30% of patients were excluded if they did not meet the angiographic criteria, even if ischemia was present to the stress test or angina, and almost 20% of patients per trial were included without demonstrable ischemia.

**Conclusion:** Clinical trials have contributed to the confusion between coronary artery disease and ischemic heart disease. This may limit the ability to interpret the results and apply them in practice.